

REMARKS

Applicants thank the Examiner for the indication of allowable subject matter with respect to claims 32 and 33. Claim 32 has been rewritten into independent form to include all of the recitations of its base claim and any intervening claims.

The present amendment is fully responsive to the Office Action having a mailing date of April 30, 2008. After entry of this amendment, claims 9, 11, 13-16 and 21-34 are pending in the Application. Claims 26 and 32 have been herein amended. Applicant submits that no new matter has been added by this amendment and that support for the claims as amended may be found throughout the specification and drawings. At least for the reasons set forth below, Applicant respectfully traverses the foregoing rejections. Further, Applicant believes that there are also reasons other than those set forth below why the pending claims are patentable, and accordingly reserves the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers.

Applicant respectfully requests reconsideration of the present Application in view of the above amendments and the following remarks.

Claim Rejections – 35 U.S.C. § 112

Claims 26 and 32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner contends that it is unclear if the guide lock recited in claims 26 and 32 is intended to be the same or different from the guide lock recited in claim 9. Claims 26 and 32 have been amended to more particularly point out and distinctly claim that the guide lock is the same guide lock as recited in claim 9. Applicant accordingly requests that the instant rejection be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 102

I. Claims 9, 14, 15, 21-24 and 30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Warner et al. (U.S. 5,871,487) (hereinafter “Warner et al.”).

A. Independent Claim 9

The rejection with respect to claim 9 is respectfully traversed. Notwithstanding, independent claim 9 has been amended to recite that the guide lock can be moved axially through application of a generally axial force to the guide lock. Warner et al. does not anticipate, teach, or suggest the claimed combination of elements. Warner et al. describes using a screw (38) that threadably engages a holding member (32) for retaining a cannula within a notch (36) of the holding member (*see Warner et al.*, column 4, lines 44-46). The Examiner contends that screw (38) corresponds to the “guide lock” of claim 9. In contrast to claim 9, screw (38) of Warner et al. cannot be moved axially through application of a generally axial force to the screw. Rather, a rotational torque must be applied to screw (38) in order to move the screw relative to holding member (32). The threaded members cannot be moved relative to one another by simply applying an axial force to one of the members, such as by pushing or pulling. Accordingly, it is respectfully requested that the instant rejection with respect to claim 9 be reconsidered and withdrawn.

B. Dependant claims 14, 15, 21-24 and 30

The rejection with respect to claims 14, 15, 21-24 and 30 is respectfully traversed. Claims 14, 15, 21-24 and 30 are dependent upon independent claim 9. The same arguments made above with respect to claim 9 are equally applicable to dependant claims 14, 15, 21-24 and 30. Nevertheless, these dependent claims also recite independently patentable subject matter.

1. Dependant claim 14

Claim 14 depends directly from claim 13. Claim 13 has not been rejected under 35 U.S.C. §102(b) as being anticipated by Warner et al., and as such, it must follow that claim 14 is also not anticipated by Warner et al.

Even if the Examiner were to determine that claim 13 is anticipated by Warner et al., claim 14 is nevertheless patentable since Warner et al. does not disclose a lip located adjacent the receptacle. Claim 14 recites that the indexing guide includes a lip adjacent to the receptacle to prevent movement of the medical instrument in a second axial direction. In paragraph 4 of the Office Action, the Examiner once again reiterates the assertion from the previous Office Action that Figure 1 allegedly shows holding member (32) having a lip disposed adjacent notch (36) for preventing axial movement of the medical device. In Applicant’s response to the Office Action

dated October 31, 2007, Applicant requested that the Examiner provide additional details as to exactly which feature of holding member (32) the Examiner believes to correspond to the “lip” of claim 14. The Examiner has not provided any additional information other than to state that the lip is shown in Fig. 1 of Warner et al.

Applicant has once again carefully reviewed both Fig. 1 and the detailed description of Warner et al. and has been unable to discern any features that would constitute a lip as described in claim 14. There is simply no feature adjacent notch (36) that would constitute a “lip” as recited in claim 14, and that would operate to prevent axial movement of a medical instrument disposed within notch (36). Indeed, notch (36) is shown to be configured as a continuous uninterrupted passage. Axial movement of the medical instrument is prevented by screw (38) engaging the medical instrument to hold it in place. It also appears from Figs. 2-4 of Warner et al. that the medical instrument may include an outwardly extending circumferential shoulder that engages an upper surface of holding member (32) when the medical instrument is located within notch (36). If it were not for these two features, neither of which remotely constitutes a “lip” as recited in claim 14, there would be nothing to prevent the medical instrument from being moved axially within notch (36). Accordingly, Applicant respectfully requests that the instant rejection with respect to claim 14 be reconsidered and withdrawn.

2. Defendant claim 15

Claim 15 recites that the cradle includes a pivotable clamp that is selectively engagable with the medical instrument. The Examiner contends that holding member (32) of Warner et al. corresponds to the “cradle” of claim 15, and that screw (48) corresponds to the “pivotable clamp”. In contrast to claim 15, however, screw (48) is not shown connected to holding member (32), which the Examiner contends corresponds to the “cradle” of claim 15, but rather is connected to second holding member (42). Accordingly, Warner et al. does not anticipate, teach or suggest the claimed subject matter of claim 15.

Applicant accordingly requests that the rejection of claims 9, 14, 15, 21-24 and 30 under 35 U.S.C. § 102(b), as being anticipated by Warner et al., be reconsidered and withdrawn.

II. Claims 9, 14 and 16 stand rejected under 35 U.S.C. §102(b), as being anticipated by Cooper et al. (U.S. 6,451,027) (hereinafter “Cooper et al.”).

A. Independent Claim 9

The rejection with respect to claim 9 is respectfully traversed. Claim 9 recites in part that the indexing guide includes at least one guide lock slidably attached to the indexing guide and selectively engagable with the portion of the medical instrument received within the receptacle to substantially prevent rotation and axially movement of the portion of the medical instrument received in the receptacle. The term “selectively engagable” means the guide lock can be moved both into and out of engagement with the medical instrument. If the guide lock cannot be alternately engaged and disengaged from the medical instrument it is not “selectively” engagable. The guide lock selectively engages the portion of the medical device received within the receptacle, which means the guide lock can be both engaged and disengaged (i.e., selectively engaged) from the medical device when the medical device is received in the receptacle. If the medical device needs to be removed for the receptacle to either engage or disengage the guide lock from the medical device, the guide lock is not capable of being selectively engaged with the medical device received in the receptacle. As will become apparent from the following discussion, Cooper et al. does not disclose a guide lock that is “selectively engagable” with the medical device received within the receptacle of the indexing guide.

The Examiner contends that mounting formation (22) of Cooper et al. (*see* Fig. 2) corresponds to the “indexing guide” of claim 9, and that endoscope locating formation (90) (*see* Figs. 10 and 11) corresponds to the “guide lock”. In contrast to claim 9, however, endoscope locating formation (90) of Cooper et al. cannot be “selectively engaged” (i.e., both engaged and disengaged) with endoscope (92) while the endoscope is received within mounting formation (22).

To engage endoscope locating formation (90) with endoscope (92), endoscope locating formation (90) is slid over a distal end of the endoscope (i.e., the end of the endoscope shown in the lower right hand corner of Fig. 11 of Cooper et al.). (*See* Cooper et al. at column 9, lines 8-21). The process of assembling endoscope locating formation (90) to endoscope (92) occurs with both members removed from mounting formation (22), at which point the endoscope locating formation is not “slidably connected” to mounting formation (22), as recited in claim 9. Endoscope locating formation (90) is secured to endoscope (92) by means of a screw-threaded fastener (90.1). The endoscope locating formation/endoscope assembly is attached to mounting formation (22) by inserting the assembly through the aperture in the mounting formation starting with the distal end of the endoscope.

To disengage endoscope locating formation (90) from endoscope (92), the endoscope locating formation/endoscope assembly is first removed from mounting formation (22) so as to access screw (90.1) that secures endoscope locating formation (90) to endoscope (92). At that point, however, in contrast to claim 9, endoscope locating formation (90) (which the Examiner contends corresponds to the guide lock of claim 9) is no longer slidably attached to mounting formation (22) (which the Examiner contends corresponds to the indexing guide of claim 9). Even if endoscope locating formation (90) could be withdrawn from mounting formation (22) far enough to access screw (90.1) without fully disengaging endoscope locating formation (90) from mounting formation (22), endoscope locating formation (90) nevertheless still could not be disengaged from endoscope (92) without first removing the endoscope from the aperture in mounting formation (22), at which point the endoscope is no longer received with the aperture. Indeed, endoscope locating formation (90) cannot be disengaged from endoscope (92) without first disengaging the endoscope from the aperture of mounting formation (22) (which the Examiner contends corresponds to the “receptacle” of claim 9). So long as any portion of endoscope (92) remains disposed within the aperture of mounting formation (22), endoscope locating formation (90) cannot be disengaged from endoscope (92). Since endoscope locating formation (90) cannot be disengaged from endoscope (92) while the endoscope is received in the aperture of mounting formation (22), endoscope locating formation (90) is not “selectively engagable” with the portion of endoscope (90) received by mounting formation (22), as recited in claim 9. Accordingly, it is respectfully requested that the instant rejection be reconsidered and withdrawn.

B. Dependant claims 14 and 16

The rejection with respect to claims 14 and 16 is respectfully traversed. Claims 14 and 16 are dependent upon independent claim 9. The same arguments made above with respect to claim 9 are equally applicable to dependant claims 14 and 16. Nevertheless, these dependent claims also recite independently patentable subject matter.

1. Claim 14

Claim 14 depends directly from claim 13. Claim 13 has not been rejected under 35 U.S.C. §102(b) as being anticipated by Cooper et al., and as such, claim 14 is also not anticipated by Cooper et al.

Even if the Examiner were to determine that claim 13 is anticipated by Cooper et al., claim 14 is nevertheless patentable since Cooper et al. does not disclose a lip located adjacent the receptacle. Claim 14 recites that the indexing guide includes a lip adjacent to the receptacle to prevent movement of the medical instrument in a second axial direction. The Examiner contends that mounting formation (22) (which allegedly corresponds to the indexing guide of claim 14) includes a lip adjacent the aperture of mounting formation (22). The Examiner does not provide any specifics as to which feature of mounting formation (22) the Examiner considers to correspond to the “lip” of claim 14. Applicant has carefully reviewed the figures and the detailed description of Cooper et al. and has been unable to discern any features that would constitute a lip as recited in claim 14. There is simply no feature adjacent the opening in mounting formation (22) that would constitute a “lip” and operate to prevent axial movement of a medical instrument disposed within the aperture. Axial movement of endoscope (92) (which presumably corresponds to the medical instrument of claim 14) is prevented by an outwardly extending circumferential shoulder of endoscope locating formation (90) (see Figs. 10 and 11 of Cooper et al.) that engages an end surface of mounting formation (22) (the surface which reference number (50) in Fig. 3 of Cooper et al. points to) and by latches (90.3) of endoscope locating formation (90) (see Fig 10) engaging corresponding apertures (no reference numbers assigned) in collar (50) (see Cooper et al., column 9, lines 22-38). Mounting formation (22) is not shown to include any projection that would operate as a “lip” to prevent axial movement of the endoscope, as recited in claim 14. If it were not for the shoulder and latches of endoscope locating formation (90), neither of which even remotely constitutes a “lip” as recited in claim 14, there would be nothing to prevent the endoscope from being moved axially within the aperture of mounting formation (22). Applicant accordingly requests that the instant rejection with respect to claim 14 be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 103

I. **Claim 11**

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Warner et al. (U.S. 5,871,487). The rejection is respectfully traversed. It is submitted that claim 11, which depends directly from claim 9, patently defines over the cited reference for the same reasons as set forth above with respect to the patentability of claim 9. Applicant accordingly requests that the instant rejection be reconsidered and withdrawn.

II. Claim 13

Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Warner et al. (US 5,871,487) in view of Moctezuma De La Barrera et al. (U.S. 7,166,144). The rejection is respectfully traversed. The Examiner contends that the balls (122) of Moctezuma De La Barrera et al. (*see* Figs. 4-6 of Moctezuma De La Barrera et al.) correspond to the “guide lock” of claim 13. Moctezuma De La Barrera et al. describes the balls as engaging a channel formed in surgical tool (156) (*see* Moctezuma De La Barrera et al., column 6, lines 40-51). Claim 13, however, recites that the guide lock engages a “notch” formed in the medical instrument. A channel is not the same thing as a notch. A channel is defined as a long groove or furrow, whereas a notch is defined as a concave cut or indentation in an edge or across a surface (*see* Webster’s New World Dictionary, 1984). If the channel is oriented circumferentially around surgical tool (156), the channel will not operate to prevent the surgical tool from being rotated relative to body (102). On the other hand, if the channel is oriented axially, it will not operate to prevent axial movement of the surgical tool relative to body (102). Either way, the channel will not prevent either rotational or axial movement of the surgical tool relative to body (102). That, of course, would be in direct contrast to the recitations of claim 13, wherein the guide lock prevents both rotation and axial movement of the medical device relative to the indexing guide. Applicant accordingly requests that the instant rejection with respect to claim 13 be reconsidered and withdrawn.

III. Claims 25-29 and 31

Claim 25-29 and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Warner et al. (US 5,871,487) in view of DE 935,625 to Bodendieck. The rejection with respect to claims 25-29 and 31 is respectfully traversed. Claims 25-29 and 31 are dependent upon independent claim 9. The same arguments made above with respect to claim 9 are equally applicable to defendant claims 25-29 and 31. Nevertheless, these dependent claims also recite independently patentable subject matter.

A. Claim 25

The rejection with respect to claim 25 is respectfully traversed. Claim 25 recites that the outer cannula is connected to the outer cannula hub and the inner cannula is attached to the

handpiece. The Examiner contends that DE 935,625 discloses a biopsy device having an outer cannula connected to a cannula hub and an inner cannula connected to a handpiece. The Examiner does not identify which feature of the inner cannula (Fig. 3 of DE 935,625) is considered to correspond to the “handpiece” of claim 25. For the sake of discussion, Applicant will assume it is the flange positioned near the end of the inner cannula opposite the tissue receiving end (i.e., the lower end of the inner cannula as shown in Fig. 3). Claim 25, however, also recites that the cradle is configured to rotatably support the handpiece therein. This was not addressed by the Examiner when setting forth the basis for rejecting claim 25. In actuality, instrument holding member (32) is not configured to rotatably support the handpiece as configured in DE 935,625. To the contrary, substantial reengineering of either instrument holding member (32) of Warner et al. or the presumptive handle portion of cannula (12) of DE 935,625, or both, would be required for the instrument holding member of Warner et al. to rotatably support the handpiece of DE 935,625. Accordingly, it is respectfully requested that the instant rejection with respect to claim 25 be reconsidered and withdrawn.

B. Claims 27-29

Claims 27-29 recite that the medical device includes a clamp selectively positionable for stabilizing the biopsy device. In formulating the rejection of claim 27-29, the Examiner does not state whether Warner et al. or DE 935,625 describes the “clamp” of claims 27-29. Indeed, this feature is not discussed at all in connection with the rejection of claims 27-29. Nevertheless, it does not appear that either reference discloses such a clamp. Accordingly, it is respectfully requested that the instant rejection with respect to claim 27-29 be reconsidered and withdrawn.

C. Claim 31

Claim 31 recites that the outer cannula hub is removably attached to the indexing guide. The Examiner has not identified which component of Warner et al. corresponds to the “indexing guide” of claim 31. The Examiner has also not identified which portion of the outer cannula shown in Fig. 2 of DE 935,625 corresponds to the “cannula hub” of claim 13. It will be assumed, however, for the sake of discussion, that the indexing guide of claim 31 corresponds to instrument holding member (32) of Warner et al., and the cannula hub corresponds to the large end portion attached to the outer cannula as shown in Fig. 2 of DE 935,625. It is plainly apparent that holding member (32) of Warner et al. cannot both be releasably attached to the

cannula hub of DE 935,625 and configured to rotatably support the handpiece of the inner cannula hub of DE 935,625 (*see* discussion above with respect to the rejection of claim 25 regarding the “handpiece”). Indeed, substantial reengineering would be required to enable the instrument holding member (32) of Warner et al. to accomplish both of these functions. Accordingly, it is respectfully requested that the instant rejection with respect to claim 31 be reconsidered and withdrawn.

CONCLUSION

All rejections have been addressed. In view of the above, the pending claims are believed to be in condition for allowance over the cited prior art. Accordingly, reconsideration and allowance are respectfully requested and the Examiner is respectfully requested to pass this application to issue. It is believed that any fees associated with the filing of this paper are identified in an accompanying transmittal. However, if any additional fees are required, they may be charged to Deposit Account 18-0013, under Order No. 65937-0047 from which the undersigned is authorized to draw. To the extent necessary, a petition for extension of time under 37 C.F.R. 1.136(a) is hereby made, the fee for which should be charged against the aforementioned account.

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